IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

KAREN HRIVNAK AND
ANDREW HRIVNAK,

Plaintiffs, Case No.:

v.

C.R. BARD, INC. AND
JOHN DOE CORPORATIONS 1-50
(fictitious),

Defendants.
_____/

COMPLAINT

1. Plaintiffs, Karne Hrivnak and Andrew Hrivnak, bring this case against Defendants for the injuries arising from the implantation into Mrs. Hrivnak of a medical device that was negligently manufactured and designed by the Defendants and failed to contain appropriate and significant warnings relating to its use.

PARTIES

2. Plaintiff, Karen Hrivnak, is, and at all times material hereto was, a resident of Hillsborough County, Florida.

3. Plaintiff, Andrew Hrivnak, who is married to Mrs. Hrivak, is, and all times material hereto was, a resident of Hillsborough County, Florida.

4. Defendant, Defendant C.R. Bard, Inc. ("Bard") is a New Jersey Corporation. At all times material, C.R. Bard, Inc. did business in New Jersey.

5. Defendant John Doe Corporations 1-50 represent presently unknown designers,

researchers, developers, manufacturers, marketers, distributors, promoters, suppliers, and sellers of the Bard Avaulta, which was and is defective and unreasonably dangerous to women.

JURISDICTION AND VENUE

8. Bard is, and at all times material hereto was, in the business of designing, manufacturing, and selling medical devices, including, but not limited to, the Bard Avaulta, in New Jersey, in the ordinary course of commerce, trade and use, all at or about the time of the injuries described herein and which were suffered by Mrs. Hrivak in Hillsborough County, Florida. Accordingly, this Court has diversity jurisdiction pursuant to 28 U.S.C § 1332.

9. Venue is proper in this District because substantial parts of the events giving rise to the causes of action set forth herein, including, without limitation, the sale and implantation of the Bard Avaulta, occurred in New Jersey.

10. All conditions precedent to the maintenance of this action have occurred, have been performed, or have been waived.

FACTUAL BACKGROUND

9. Defendant Bard and John Doe Corporations 1-50 (collectively "Defendants") at all times material hereto, were engaged in the business of placing medical devices into the stream of commerce by designing, manufacturing, marketing, packaging, labeling, and selling such devices, including the Bard Avaulta (also referred to herein as the "Medical Device").

10. The Bard Avaulta is an implantable, mesh , pelvic floor support device designed to treat pelvic organ prolapse ("POP") and relieve the pain, discomfort, and bladder control issues that accompany POP.

11. Statements made to the FDA during the 510(k) approval process for this Medical Device inadequately relied on predicate devices and not clinical testing or other design verification or

testing. These statements induced the Plaintiffs into relying upon the Defendants' judgment.

11. The Medical Device was designed to be implanted in such a way that it would provide support for eroded or weakened muscles and support the pelvic floor.

12. The Medical Device is comprised of non-woven polypropylene fibers. The Bard Avaulta is part of a line of transvaginal mesh products manufactured, marketed, packaged, labeled, and sold by the Defendants. The Defendants' entire line of transvaginal mesh products share common defects in design, warnings, and manufacture.

13. On October 20, 2008, the Food and Drug Administration (hereinafter, "FDA") issued a Public Health Notification that described over 1,000 complaints that had been reported over a three year period related to vaginal sling implants.

14. Due to defects in design, manufacture, and warnings, the Bard Avaulta implanted into Mrs. Hrivnak was unreasonably dangerous at the time it left Defendants' control.

Plaintiffs' Experience and Injuries

15. On May 30, 2008, Mrs. Hrivnak was implanted with a Bard Avaulta posterior pelvic support system which was designed, manufactured, packaged, labeled, marketed, and sold by Defendants.

16. The Medical Device was implanted into Mrs. Hrivnak with the intention of treating her POP, a use for which Defendants marketed and sold these products.

17. At all times, the Bard Avaulta that was implanted in Ms. Hrivnak was used for the purpose that Defendants marketed the product.

18. After, and as a result of the surgical implant of Defendants' Medical Device, Mrs. Hrivnak suffered serious bodily injuries, including extreme pain, bladder spasms, continued urinary incontinence, erosion of her internal bodily tissue, and other injuries similar to the ones

described in the FDA's Public Health Advisory of October 20, 2008.

19. These injuries would not have occurred but for the defective nature of the product implanted and/or Defendants' wrongful conduct.

20. As a result of having the Bard Avaulta, Mrs. Hrivnak has experienced significant mental and physical pain and suffering, undergone multiple surgeries and revisionary procedures, and she has sustained permanent injuries.

COUNT I

(Strict Liability – Defective Design or Manufacture, by Plaintiff, Karen Hrivnak)

21. This is an action for damages in excess of $75,000.00, exclusive of interest, costs and attorneys fees.

22. Plaintiffs adopt and reallege paragraphs 1 through 20 above though fully set forth herein.

23. Defendants placed the Bard Avaulta into the stream of commerce with the actual or constructive knowledge that it would be used without inspection for defects.

24. The Medical Device was defective in its manufacture or design.

25. Because of defects in the Medical Device, it is, and at all times material hereto was, unreasonably dangerous.

26. As a direct and proximate result of the defective and unreasonably dangerous Medical Device, Mrs. Hrivnak suffered extreme pain, bladder spasms, continued urinary incontinence, erosion of her internal bodily tissue that has resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition, and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

WHEREFORE, Plaintiff, Karen Hrivnak respectfully demands that this Honorable Court enter judgment against Defendants, Bard and John Doe Corporations 1 -50, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT II

(Strict Product Liability – Failure to Warn, by Plaintiff, Karen Hrivnak)

27. This is an action for damages in excess of $75,000.00, exclusive of interest, costs and attorneys' fees.

28. Plaintiffs adopt and reallege paragraphs 1 through 20 above though fully set forth herein.

29. The Medical Device implanted in Mrs. Hrivnak was defective and unreasonably dangerous when it left the possession of the Defendants in that it contained warnings which were inadequate and insufficient to alert physicians or consumers to the dangerous risks associated with the product, including, without limitation, extreme pain, bladder spasms, continued urinary incontinence, erosion of internal bodily tissue, and other injuries similar to the ones described in the FDA's Public Health Advisory of October 20, 2008.

30. The Medical Device implanted in Mrs. Karen Hrivnak was used for its intended purpose, *i.e.*, the correction of POP.

31. Mrs. Hrivnak's physicians, including the surgeon who performed the implant of the Medical Device, could not have discovered any defect with the product through the exercise of care.

32. Mrs. Hrivnak's physicians, including the surgeon who performed the implant of the Medical Device, did not have substantially the same knowledge that an adequate warning from the manufacturer or a distributor would have communicated.

33. The warnings that were provided by Defendants regarding the Medical Device were not sufficient, accurate, clear, or ambiguous.

34. The Defendants had a continuing duty to warn Mrs. Hrivnak's or her doctors of the dangers associated with the Medical Device

35. As a direct and legal result of the Defendants' failure to warn, Plaintiff, Karen Hrivnak has sustained serious and permanent injuries, including, but not limited to, extreme pain, bladder spasms, continued urinary incontinence, erosion of her internal bodily tissue, and other injuries similar to the ones described in the FDA's Public Health Advisory of October 20, 2008

36. WHEREFORE, Plaintiff, Karen Hrivnak, respectfully demands that this Honorable Court enter judgment against Defendants, Bard and John Doe Corporations 1 - 50, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT III

(Negligence, by Plaintiff, Karen Hrivnak)

37. This is an action for damages in excess of $75,000.00, exclusive of interest, costs and attorneys' fees.

38. Plaintiffs adopt and reallege paragraphs 1 through 20 above as if fully set forth herein.

39. Defendants owed a duty to Plaintiffs and others similarly situated as foreseeable users of the Medical Device to manufacture and sell it so that they would be reasonably safe for its intended use and free from defects.

40. Defendants were negligent in designing, manufacturing and selling the Medical Device by, among other things, failing to properly fabricate the Medical Device, failing to adequately test the Medical Device, and failing to conduct adequate quality control procedures for the Medical Device.

41. As a direct and proximate result of the foregoing negligence of Defendants; Plaintiff, Karen Hrivnak has suffered extreme pain, bladder spasms, continued urinary incontinence, erosion of her internal bodily tissue that has resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

42. WHEREFORE, Plaintiff, Karen Hrivnak, respectfully demands that this Honorable Court enter judgment against Defendants, Bard and John Doe Corporations 1 - 50 for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT IV

(Breach of Warranty, by Plaintiff, Karen Hrivnak)

43. This is an action for damages in excess of $75,000.00, exclusive of interest, costs and attorneys' fees.

44. Plaintiffs adopt and reallege paragraphs 1 through 20 above as though fully set forth herein.

45. Defendants impliedly warranted to Plaintiffs and all others similarly situated that the Medical Device was reasonably fit for its intended use and that it was designed, manufactured and sold in accordance with good design, engineering, and industry standards.

46. The Medical Device was defective in its manufacture or design and was therefore, not fit for its intended use and was not designed, manufactured, or sold in accordance with good design, engineering, and industry standards.

47. Defendants breached the above warranties in that the Medical Device was defective as set forth above, was not for its intended use and was not designed, manufactured, or sold in

accordance with good design, engineering and industry standards.

48. As a direct and proximate result of the foregoing breaches of warranties, Plaintiff suffered extreme pain, bladder spasms, continued urinary incontinence, erosion of her internal bodily tissue that has resulted in pain and suffering, disability, mental anguish, loss of capacity for the enjoyment of life, expenses of hospitalization, medical and nursing care and treatment, aggravation of a preexisting condition and interest on the foregoing. The foregoing losses and injuries are either permanent or continuing and Plaintiff will suffer the losses in the future.

49. WHEREFORE, Plaintiff, Karen Hrivnak, respectfully demands that this Honorable Court enter judgment against Defendants, Bard and John Doe Corporations 1 - 50, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein.

COUNT V

(Loss of Consortium, by Plaintiff, Andrew Hrivnak)

50. This is an action for damages in excess of $75,000.00, exclusive of interest, costs and attorneys' fees.

51. Plaintiffs adopt and reallege paragraphs 1 through 20 above as though fully set forth herein.

52. As a result of the surgical implant of Defendants' Medical Device in Mrs. Hrivnak, the Plaintiff, Andrew Hrivnak has been damaged and has lost the support, services, comfort, society, and attentions in the past and will suffer such losses in the future.

WHEREFORE, Plaintiff, Andrew Hrivnak, respectfully demands that this Honorable Court enter judgment against Defendants, Bard and John Doe Corporations 1 - 50, jointly and severally for damages, together with costs of this action, and demands trial by jury of all issues raised herein

JURY TRIAL DEMAND

Plaintiffs demand a jury trial on all issues so triable.

Dated this 20 day of October, 2010.

By: _____

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